UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,266	08/26/2003	Howard R. Levin	JHN-3659-71	2067

23117 7590 05/18/2007
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
HAND, MELANIE JO	
ART UNIT	PAPER NUMBER
3761	
MAIL DATE	DELIVERY MODE
05/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/647,266	LEVIN ET AL.	
	Examiner	Art Unit	
	Melanie J. Hand	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

As an initial matter, claims 53 and 54 were rejected under 35 U.S.C. 103 over Truitt in view of Glantz, not claims 53-59. Examiner assumes that applicant's arguments traversing the rejection of claims 54-59 were intended to be based upon arguments traversing the rejection of claim 53 from which claims 55-59 depend.

Applicant's arguments, see Remarks, page 5, filed February 27, 2007, with respect to the rejection of claim 55 under 35 U.S.C. 112 have been fully considered and are persuasive. The rejection has been withdrawn.

Applicant's arguments filed February 27, 2007 have been fully considered but they are not persuasive.

With respect to applicant's arguments regarding the rejection of claims 53 and 54 over Truitt in view of Glantz: Applicant argues that Truitt does not teach a peripheral access catheter. Nowhere in Truitt is it specifically taught that the vein from which blood is withdrawn is a central vein, so it is unclear what basis applicant has for this statement. The Office has already acknowledged that Truitt does not teach a peripheral vein explicitly, hence the rejection under 35 U.S.C. 103.

Applicant further argues that Glantz teaches locating a catheter tip in a patient's heart. Again, nowhere in Glantz is this explicitly taught. Reading the figures and the specification together, it is easily concluded that the closest the PICC catheter gets to a heart is the superior vena cava, which carries blood to the heart but is not considered herein to be part of the heart. The locator 240 is the only device that appears to be located in the heart itself, however the locator is not the catheter or catheter tip and is even referring to another piece of prior art, not a

teaching of a structural element by Glantz. Even if it were, location of the catheter tip in the heart would just be one intended use of the method of Glantz, and does not render the claimed invention patentable on that ground.

As to applicant's arguments regarding the prior art of Jaski, Applicant is correct in noting that Jaski is no longer being used in a grounds of rejection, therefore Examiner is not addressing applicant's arguments on the prior art of Jaski. Jaski was introduced previously to remedy the deficiency of the combined teaching of Truitt and Glantz with respect to a blood flow rate. Therefore, Jaski does not address properly the non-obviousness of the claimed invention and thus can hardly be considered evidence of the non-obviousness of the claimed invention. The fact that Jaski teaches that the instant report is "the first clinical report of rapid removal of extracellular and intravascular fluid vvolume excess via ultrafiltration without use of a central venous catheter" does not constitute sufficient proof that a) use of a catheter other than a central access catheter in ultrafiltration is more correct, more desirable or non-obvious in any way, nor b) that use of a catheter other than a central access catheter in any of the other methods claimed (i.e. hemofiltration or dialysis) is more correct, more desirable or non-obvious in any way.

Terminal Disclaimer

The terminal disclaimer filed on February 27, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,685,664 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

Claims 53-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The newly added method step of "attempting to withdraw" is indefinite as it is not an action and encompasses an indefinite number of embodiments in which withdrawal is successful or unsuccessful.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 53-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Truitt et al. (U.S. Patent No. 5,910,252) in view of Glantz (U.S. Patent No. 5,749,835).

With respect to **claims 53,54:** Truitt teaches of a method for treating blood extracorporeal, such as by hemofiltration, hemodialysis (i.e. dialysis), or ultrafiltration. The system used to perform the treatment method comprises a catheter inserted into a vein or artery of a patient, which serves as a blood withdrawal line, and a device line (i.e. withdrawal blood tube) that supplies the withdrawn blood to the apparatus to process the blood according to a selected treatment protocol. With respect to applicant's limitation of the catheter being inserted into a large vein, great vein, or vena cava to access a reservoir of blood for continuous blood withdrawal, this step is considered to be met since the vein catheterized may be considered a large vein. The system also includes a pump connected to the withdrawal line and allows for continuous treatment by extracorporeally removing solutes from the blood. For example, in ultrafiltration the removal is excess water. The pump creates a negative pressure in the catheter, which is

higher than the blood pressure in the vein or artery in which the catheter is inserted. The pump supplying negative pressure is seen to be equivalent to applying suction. With respect to claim 55, Truitt teaches that the claimed blood flow through the needle or catheter being less than 40 milliliter per minute, it is the position of the examiner that the blood treatment system of Truitt is capable of performing these rates since the system includes a programmable controller that regulates the pumps of the system. Such flow rates would have been obvious to one of ordinary sill at the time of the invention since these procedures are always modified on a patient-by-patient basis.

Glantz discloses a PICC catheter for use or placement within a peripheral vein, such as the cephalic vein, via the patient's arm. The catheter is then moved to place the tip in a desired location, such as in the superior vena cava. Glantz also teaches that, as is well known in the art, the caregiver determines the length the PICC is needed on a per patient basis (see col. 5, lines 38-63 and figures 5, 6 & 6A). With respect to the claim 54, it would have been obvious to choose a catheter having a length of 35 cm to 40 cm that may be advanced into a large or great vein since it would have been obvious to choose a length within this range, since it has been held that the discovering of an optimum value of a result effective variable involves only routine skill in the art. Furthermore, it is well known in the art, as well as taught by Glantz, that the determination of length of a PICC catheter, as well as any other catheter type used in a medical procedure, is a length determined to equal the distance between the entry site and the desired location of the catheter tip. Glantz also teaches that, as is well known in the art, the caregiver determines the length the PICC is needed on a per patient basis (see col. 5, lines 38-63 and figures 5, 6 & 6A). Therefore, this determination must be based on a patient-by-patient basis to customize the size based on the patient's anatomy and any other medical conditions that may need to be taken into consideration.

It would have been obvious to one having ordinary skill in the art, at the time of the invention, to modify the method of Truitt to include the step of inserting the catheter into a peripheral vessel, such as the cephalic artery, into the vena cava to withdraw blood into the extracorporeal circuit as the connection site. Further, it would have been obvious to substitute the catheter of Truitt with a catheter as taught by Glantz to have a catheter that is of a length that may be advanced in a large or great vein, the that is used to be a catheter that is at least 25 cm, the catheter that is used to be not greater than 75 cm long, since it would have been obvious to one having ordinary skill in the art to use a catheter having any of these dimensions, since it has been held that the discovering of an optimum value of a result effective variable involves only routine skill in the art. Furthermore, it is well known, as taught by Glantz, that the determination of length of a catheter used in a medical procedure is a determination based on a patient-by-patient basis to customize the size based on the patient's anatomy and any other medical conditions that may need to be taken into consideration.

Claims 55-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Truitt et al. ('252) in view of Glantz ('835) as applied to claims 53 and 54 above and further view of Pizziconi et al (U.S. Patent No. 4,832,034)

With respect to **claim 55:** The combined teaching of Truitt and Glantz fails to disclose the step of determining that the blood flow rate is insufficient if said blood flow rate through a needle is less than 40 milliliter per minute. Pizziconi teaches a blood filtration process having a blood flow rate of 60 ml/minute. Pizziconi teaches that filtration rate increases moderately as blood flow rate increases, therefore it would be obvious to one of ordinary skill in the art to make a determination that blood flow rate is insufficient at a flow rate of less than 40 mL per minute as a

higher flow rate would achieve a more desired filtration rate as taught by Pizziconi. (Col. 26, lines 50-62, Figs. 6,8)

With respect to **claim 56-59:** Pizziconi teaches ultrafiltration (claims 56,59, Fig. 9 of Pizziconi), hemofiltration (claim 57, Fig. 6 of Pizziconi), and dialysis (claim 58, Fig. 6 of Pizziconi) and teaches that a catheter is placed in a vein for five hours. Pizziconi teaches that increased filtration time improves filtration rate, therefore it would be obvious to one of ordinary skill in the art to modify the method taught by the combined teaching of Truitt and Glantz by positioning a catheter in a patient's vein for five hours to improve filtration rate as is taught by Pizziconi.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

May 11, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER